



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

the Application of) Examiner: Diana B. Johannsen
Paolo Fortina et al.)
Serial No. 10/606,133) Art Unit: 1634
Filed: June 25, 2003) Our File No: CHOP.0182US
For: "Methods for Detection of)
Genetic Alterations)
Associated with Cancer")

TRAVERSAL AND REQUEST FOR

RECONSIDERATION OF REQUIREMENT FOR RESTRICTION

At the outset it is noted that a shortened statutory response period of one (1) month was set forth in the Official Action dated March 13, 2006 in the above-identified patent application. Therefore, the initial due date for response was April 13, 2006. A petition for a two (2) month extension of the response period is presented with this response, which is being filed within the two month extension period.

A restriction requirement under 35 U.S.C. §121 was set forth in the March 13, 2006 Official Action. It is the Examiner's position that claims 1-8 in the present application are drawn to more than one patentably distinct invention. Specifically, the Examiner has required Applicants to "elect an alteration or combination thereof from those set forth in dependent claims 2, 4, 5, and 8."

Applicants strenuously disagree with the Examiner's position and submit that a withdrawal of the instant restriction requirement is clearly in order for the following reasons.

According to the MPEP at §803, two criteria must be satisfied in order to warrant restriction, namely the inventions must be independent or distinct and there must be a serious burden on the Examiner if the restriction is not

required.

The terms "independent" and "distinct" are defined at MPEP §802.01. Specifically, "the term 'independent' (i.e., not dependent) means that there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect." Additionally, "related inventions are distinct if the inventions as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER (though they may each be unpatentable over the prior art)."

Notwithstanding the Examiner's assertion to the contrary, it is apparent from an objective reading of the claims that they are drawn to closely related subject matter and, therefore, do not comprise separate and distinct inventions. In order to be considered independent, there must be no "disclosed relationship" between the two or more subjects; i.e., they are unconnected in "design, operation, and effect." Applicants submit that claim 1-8 are all clearly drawn to methods for detecting the presence or absence of at least one genetic alteration in a target nucleic acid for the diagnosis and management of malignant disease. Furthermore, all of the methods comprise providing a target nucleic acid and assessing the target nucleic acid for the loss of heterozygosity. Accordingly, Applicants submit that it is clear that the claims of the instant invention have a "disclosed relationship" and are connected in design, operation, and effect.

Applicants also note that in order for a restriction to be proper, the restricted subject matter must be "distinct," i.e., the restricted subjects must be "PATENTABLE (novel and unobvious) OVER EACH OTHER." By inference, it appears to Applicants that the Examiner contends that a claim drawn to a method for determining the presence or absence of at least one

genetic alteration in a target nucleic acid for the diagnosis and management of malignant disease comprising providing a target nucleic acid and assessing the target nucleic acid for loss of heterozygosity, wherein the genetic alteration is a deletion of at least one nucleotide, is novel and unobvious over the same method wherein the genetic alteration is, for example, an insertion or inversion of at least one nucleotide.

Additionally, the MPEP at §803 states that "if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions." In contrast to the Examiner's position, it is apparent that the claims that they are drawn to closely related subject matter and the examination of claims 1-8 together cannot be reasonably regarded as imposing a "serious burden" on the Examiner. Indeed, all of the claimed methods comprise essentially the same method steps regardless of the genetic alteration selected from the Markush group recited in claim 2.

Furthermore, Applicants take particular exception to the Examiner's requirement for the election of an invention as opposed to an election of a species. The MPEP at §803.02 states that "in applications containing a Markush-type claim that encompasses at least two independent or distinct inventions, the examiner may require a provisional election of a single species prior to examination on the merits." "Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability." "Should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended." Applicants respectfully submit that in the instant application a requirement for an election of species is

clearly more appropriate and consistent with the guidance provided in the MPEP than a restriction requirement, if any type of restriction must be made at all, which Applicants dispute for the reasons set forth above. Indeed, the requirement for a species election would be less restricting and allow for the examination of the subject matter which Applicants regard as their invention.

For the foregoing reasons, Applicants respectfully request withdrawal or, at the very least, modification of the present restriction requirement.

In order to be fully responsive to the instant restriction requirement, Applicants hereby elect, with traverse, the genetic alteration of deletion.

Applicants hereby reserve the right to file one or more continuing applications, as provided in 35 U.S.C. §120, on the subject matter of any claims finally held withdrawn from consideration in this application.

Early and favorable action on the merits of this application is respectfully solicited.

Respectfully submitted,
DANN DORFMAN HERRELL and SKILLMAN, P.C.
Attorneys for Applicant

By 
Robert C. Netter, Jr., Ph.D.
PTO Registration No. 56,422

Telephone: (215) 563-4100